

II. Support for the Amended and Newly Added Claims

Claim 1 has been amended to recite that the isolated nucleic acid molecule comprises a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2. Support for this claim can be found throughout the specification as originally filed, with particular support being found in original claim 1.

Claim 2 has been amended to correct a minor grammatical error.

Claim 3 has been added to specifically recite an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in Section 5.1.

Claim 4 has been added to specifically recite an isolated expression vector comprising the nucleotide sequence of SEQ ID NO:1. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in Section 5.1.

Claim 5 has been added to specifically recite a host cell comprising the expression vector of claim 2. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 17, lines 13-17.

It will be understood that no new matter is included within the amended or newly added claims.

III. Rejection of Claims 1 and 2 Under 35 U.S.C. § 101

The Action first rejects claims 1 and 2 under 35 U.S.C. § 101, as allegedly lacking a patentable utility. Applicants respectfully traverse.

The present invention has a number of substantial and credible utilities, not the least of which is in diagnostic assays, as described in the specification, at least at page 14, lines 5-8. As described in the specification at page 7, lines 21-30, the present sequences define two coding single nucleotide polymorphisms - specifically, a T/G polymorphism at position 233 of SEQ ID NO:1, which can lead to a valine or glycine residue at amino acid position 78 of SEQ ID NO:2, and a C/T polymorphism at position 316 of SEQ ID NO:1, which can lead to an arginine or cysteine residue at amino acid position 106 of SEQ ID NO:2. As such polymorphisms are the basis for diagnostic assays such as forensic analysis, which does not require the identification of a specific medical condition, and is undoubtedly a "real world" utility, the

present sequences must in themselves be useful. It is important to note that the presence of more useful polymorphic markers for forensic analysis would not mean that the present sequences lack utility. As clearly set forth by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991):

An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Just because other polymorphic sequences from the human genome have been described does not mean that the use of the presently described polymorphic markers for forensic analysis is not a specific utility.

As admitted in the Action, the present application describes a novel G-protein coupled receptor. Of the pharmaceutical products currently being market by the entire industry, 60% of these drugs target G-protein coupled receptors (Gurrath, 2001, *Curr. Med. Chem.* 8:1605-1648). Given that more than half of the currently marketed drugs target proteins that are structurally (7TM proteins) and functionally (G-protein interaction) related to the presently described sequences, a preponderance of the evidence clearly weighs in favor of Applicants' assertion that the skilled artisan would readily recognize that the presently described sequences have a specific (the claimed GPCR proteins are encoded by a specific locus on the human genome), credible, and well-established utility, for example in tracking gene expression. As an additional example of the utility of the present nucleotide sequences, the specification details on page 9, lines 15-17, that the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips. Such "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents, as exemplified by U.S. Patent Nos. 5,445,934, 5,556,752, 5,744,305, 5,837,832, 6,156,501 and 6,261,776. As the present sequences are specific markers of the human genome (see below), and such specific markers are targets for the discovery of drugs that are associated with human disease, those of skill in the art would instantly recognize that the present nucleotide sequences would be an ideal, novel candidate for assessing gene expression using such DNA chips. Given the widespread utility of such "gene chip" methods using *public domain* gene sequence information, there can be little doubt that

the use of the presently described *novel* sequences would have great utility in such DNA chip applications. Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful.

Evidence of the "real world" substantial utility of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Perhaps the most notable gene chip company is Affymetrix. However, there are many companies which have, at one time or another, concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, for example: Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. In addition, two such companies (Agilent acquired by American Home Products and Rosetta acquired by Merck) were viewed to have such "real world" value that they were acquired by large pharmaceutical companies for significant sums of money. The "real world" substantial industrial utility of gene sequences or fragments would, therefore, appear to be widespread and well established. Clearly, persons of skill in the art, as well as venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data in general, and specifically human genomic data. Billions of dollars have been invested in the human genome project, resulting in useful genomic data (see, *e.g.*, Venter *et al.*, 2001, *Science* 291:1304). The results have been a stunning success as the utility of human genomic data has been widely recognized as a great gift to humanity (see, *e.g.*, Jasny and Kennedy, 2001, *Science* 291:1153). Clearly, the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible (worthy of billions of dollars and the creation of numerous companies focused on such information) and well-established (the utility of human genomic information has been clearly understood for many years).

Although Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), as a further example of the utility of the presently claimed polynucleotide, as described in the specification at least at page 3, lines 36-37, the present nucleotide sequences have a specific utility in "mapping a unique gene to a particular chromosome". This is evidenced by the fact that

SEQ ID NO:1 can be used to map SEQ ID NO:1 to chromosome 11 (present within two independent chromosome 11 clones; Genbank Accession Numbers AC116156 and AC109341; alignments and the first page from the Genbank reports are presented in **Exhibit C**). Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of human chromosome 11 that contains the gene encoding the given polynucleotide, a utility not shared by virtually any other nucleic acid sequences. In fact, it is this specificity that makes this particular sequence so useful. Early gene mapping techniques relied on methods such as Giemsa staining to identify regions of chromosomes. However, such techniques produced genetic maps with a resolution of only 5 to 10 megabases, far too low to be of much help in identifying specific genes involved in disease. The skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the human genome, such as the present nucleic acid sequence.

Applicants respectfully remind the Examiner that only a minor percentage (2-4%) of the genome actually encodes exons, which in-turn encode amino acid sequences. The presently claimed polynucleotide sequence provides biologically validated empirical data (*e.g.*, showing which sequences are transcribed and polyadenylated) that *specifically* define that portion of the corresponding genomic locus that actually encodes exon sequence, as described above. Applicants respectfully submit that the practical scientific value of biologically validated, expressed and polyadenylated mRNA sequences is readily apparent to those skilled in the relevant biological and biochemical arts. For further evidence in support of the Applicants' position, the Examiner is requested to review, for example, section 3 of Venter *et al.* (*supra* at pp. 1317-1321, including Fig. 11 at pp.1324-1325), which demonstrates the significance of expressed sequence information in the structural analysis of genomic data. The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome essentially as described in the Venter *et al.* article. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Rather, as set forth by the Federal Circuit, "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534

(1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable (*State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 206 USPQ 193 (S.Ct. 1980)).

The Action states that the present sequence lacks utility because any "particular mental, biological or medical disorder of disease" is not disclosed (Action at page 4). However, this is not the standard required for utility under 35 U.S.C. § 101. In *In re Brana*, (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent

protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted. The Action states that the claimed sequences lack utility because "further research" (Action at page 5) would be required in certain aspects of the invention. Even if, *arguendo*, further research might be required in certain aspects of the present invention, this does not preclude a finding that the invention has utility, as set forth by the Federal Circuit's holding in *Brana*, which clearly states, as highlighted in the quote above, that "pharmaceutical inventions, necessarily includes the expectation of further research and development" (*Brana* at 1442-1443, emphasis added). In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Finally, the requirements set forth in the Action for compliance with 35 U.S.C. § 101 do not comply with the requirements set forth by the Patent and Trademark Office ("the PTO") itself for compliance with 35 U.S.C. § 101. While Applicants are well aware of the new Utility Guidelines set forth by the USPTO, Applicants respectfully point out that the current rules and regulations regarding the examination of patent applications is and always has been the patent laws as set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Applicants are unaware of any significant recent changes in either 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. This is underscored by numerous patents that have been issued over the years that claim nucleic acid fragments that do not comply

with the new Utility Guidelines. As examples of such issued U.S. Patents, the Examiner is invited to review U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,281 (each of which claims short polynucleotides), and recently issued U.S. Patent No. 6,340,583 (which includes no working examples), none of which contain examples of the "real-world" utilities that the Examiner seems to be requiring. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section IV, below), Applicants submit that the present polynucleotides must also meet the requirements of 35 U.S.C. § 101. While Applicants understand that each application is examined on its own merits, Applicants are unaware of any changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly non-statutory or failing to meet the requirements of 35 U.S.C. § 101. Thus, holding Applicants to a different standard of utility would be arbitrary and capricious, and, like other clear violations of due process, cannot stand.

For each of the foregoing reasons, Applicants submit that as the presently claimed nucleic acid molecules have been shown to have a substantial, specific, credible and well-established utility, the rejection of claims 1 and 2 under 35 U.S.C. § 101 has been overcome, and request that the rejection be withdrawn.

IV. Rejection of Claims 1 and 2 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1 and 2 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1 and 2 have been shown to have "a specific, substantial, and credible utility", as detailed in section III above, the present rejection of claims 1 and 2 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claims 1 and 2 under 35 U.S.C. § 112, first paragraph, be withdrawn.

V. **Rejection of Claim 1 Under 35 U.S.C. § 112, Second Paragraph**

The Action next rejects claim 1 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

The Action rejects claim 1 as allegedly indefinite based on the term "stringent hybridization conditions", because the specific hybridization and washing conditions are not recited in the claim. Applicants stress that "a claim need not 'describe' the invention, such description being the role of the disclosure". *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). However, while Applicants submit that the term is sufficiently definite, as a number of stringent hybridization conditions are defined in the specification and would be known to those of skill in the art, solely in order to progress the case more rapidly toward allowance the claim has been revised to remove the term "hybridizes under stringent conditions". Applicants therefore request withdrawal of this rejection.

VI. **Rejection of Claim 1 Under 35 U.S.C. § 102(a)**

The Action next rejects claim 1 under 35 U.S.C. § 102(a), as allegedly anticipated by Bellenson *et al.* (WO01/27158, 19 April, 2001; "Bellenson"). The Action bases this rejection on the denial of priority to provisional application 60/221,012. This is **completely** improper. As set forth in the Manual for Patent Examination Procedure ("MPEP"), Section 201.15, "(t)he most important aspect of the examiner's action pertaining to a right of priority is the determination of the identity of invention between" the two applications (MPEP, page 200-96). Importantly, the present application and provisional application 60/221,012 are nearly *verbatim* identical. Therefore, there can be **no doubt** that the presently claimed invention was properly disclosed in provisional application 60/221,012. Applicants therefore request that the denial of priority to the claimed provisional application 60/221,012 be withdrawn.

It is well-known that to qualify as prior art, a reference must be "known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent" (35 U.S.C. § 102(a), emphasis added). The date that Bellenson was described in a printed publication was April 19, 2001. The present application, filed on July 26, 2001, properly claims the benefit of U.S. Provisional Application Number 60/221,012, which was filed on July

27, 2000, over 9 months before the Bellenson sequence became publicly available. Therefore, as Bellenson is not properly used as prior art against the present application, Applicants submit that the present rejection of claim 1 under 35 U.S.C. § 102(a) is improper, and should be withdrawn.

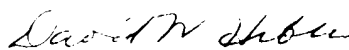
However, while Applicants in **no way** agree with the present rejection, as claim 1 has been amended to recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2, which is neither taught nor suggested by Bellenson, Applicants submit that the rejection of claim 1 under 35 U.S.C. § 102(a) has been rendered moot, and respectfully request withdrawal of the rejection.

VII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Ulm have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

March 3, 2003
Date



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PATENT TRADEMARK OFFICE

Exhibit B

Marked Up Version of Amended Claims in U.S. Patent Application Ser. No. 09/916,122

1. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:
 - (a) encodes at least fifty contiguous the amino acids shown in SEQ ID NO:2; and
 - (b) hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO:1 or the complement thereof] encodes the amino acid sequence of SEQ ID NO:2.
2. (Amended) An isolated nucleic acid expression vector comprising a nucleotide sequence encoding the amino acid sequence [described in] of SEQ ID NO: 2, said vector having the property of being capable of expressing the amino acid sequence of SEQ ID NO: 2 when present in a suitable host cell.
3. (New) The isolated nucleic acid molecule of claim 1, wherein said nucleotide sequence comprises the sequence of SEQ ID NO:1.
4. (New) The isolated nucleic acid expression vector of claim 2, wherein said nucleotide sequence comprises the sequence of SEQ ID NO:1.
5. (New) A host cell comprising the expression vector of claim 2.

Query= SEQ ID NO:1
 (975 letters)

Sequences producing significant alignments:	Score (bits)	E Value
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Sbjct: 58632 gaaataagatcttag 58618